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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. 99N–2098]**

# Computer-Controlled Potentially High Risk Medical Devices—List of Device Types

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Computer-Controlled Potentially High Risk Medical Devices—List of Device Types.'' FDA has developed a list of types of computer-controlled, potentially high-risk medical devices that have the potential for the most serious consequences for the patient should they fail because of date-related problems. This list will be useful to FDA, manufacturers, and health care facilities as they prioritize and assess their efforts to prevent potential Year 2000 (Y2K) problems with medical devices. This list has previously been made available on FDA's web site.

**FOR FURTHER INFORMATION CONTACT:** Thomas B. Shope, Center for Devices and Radiological Health (HFZ–140), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–3314, ext. 32.

**SUPPLEMENTARY INFORMATION:**

## I. Background

In order to more sharply focus agency efforts related to the possible impact of the Y2K date problem on medical devices, FDA has developed a list of types of computer-controlled, potentially high-risk medical devices that have the potential for the most serious consequences for the patient should they fail. Inclusion of a type of device on this list does not mean that all devices of this type have a date-related problem (are Y2K noncompliant) or, if they are Y2K noncompliant, that



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they necessarily pose a significant risk to patients. Rather, this list includes those types of devices that could pose a risk to patients if the date-related failure affects the function or operation of the device. FDA will use this list to identify those devices (and manufacturers) that would present the most serious risks to patients if they experienced a Y2K related failure. This will help the agency to focus attention on the devices that could present the highest levels of risk.

The list includes the types of computer-controlled devices whose failure to function as designed or expected could result in immediate and serious adverse health consequences. These potentially high-risk devices are those that are:

1. Used in the direct treatment of a patient where device failure could compromise the treatment or could injure the patient, or

2. Used in the monitoring of vital patient parameters and whose data are immediately necessary for effective treatment, or

3. Necessary to support or sustain life during treatment or patient care.

The list does not include diagnostic devices whose failure would not result in immediate harm to the patient, even though the diagnostic information they provide might be unavailable or incorrect. However, a few diagnostic devices have been included, if the results of calculations or other information processing by the device would not be readily apparent to the user, and a Y2K failure of the device could reasonably lead to serious adverse health consequences before being detected by the user.

This list of computer-controlled potentially high-risk devices will be used by FDA for several purposes and can also provide a guide to health care facilities regarding the types of devices that should receive priority in their assessment and remediation of medical devices.

FDA will identify all manufacturers of these types of devices. These manufacturers will be candidates for further oversight to provide increased assurance that product Y2K status has been carefully assessed and that any Y2K-related upgrade has been developed and tested in accordance with the quality system regulations. That oversight may include facility inspection or audit. FDA

will also ascertain whether these manufacturers have made Y2K status information available to users, and that, where appropriate, users have received notification regarding any remedial action that may be necessary.

This list should not be considered a definitive list of all high-risk devices. It was developed by FDA staff based on their assessment of the types of devices that have the greatest potential for direct patient risk should they fail to correctly process date-related information. FDA will update the list, if necessary.

**II. Electronic Access**

In order to receive a copy of ''Computer-Controlled Potentially High Risk Medical Devices—List of Device Types'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1142) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the list may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes ''Computer-Controlled Potentially High Risk Medical Devices—List of Device Types,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''. ''Computer-Controlled Potentially High Risk Medical Devices—List of Device Types'' will also be available at ''http://www.fda.gov/cdrh/yr2000/cdrh/phrds/phrds.html''.

## III. List of Potentially High Risk Devices

The following list contains the potentially high-risk device types. Where the generic device type has been classified by FDA, the list includes the section number in Title 21 of the Code of Federal Regulations where the device type is described. For those devices cleared for market through the premarket approval application process or which have not yet been classified, no classification regulation number is given.

*A. Classified Devices*

(Classification regulation number followed by classification name)

862.1345 Glucose Test System

862.2140 Centrifugal Chemistry Analyzer for Clinical Use

862.2150 Continuous Flow Sequential Multiple Chemistry Analyzer for Clinical Use

862.2160 Discrete Photometric Chemistry Analyzer for Clinical Use

862.2170 Micro Chemistry Analyzer for Clinical Use

868.1150 Indwelling Blood Carbon Dioxide Partial Pressure ($P_{CO2}$) Analyzer

868.1200 Indwelling Blood Oxygen Partial Pressure ($P_{02}$) Analyzer

868.1730 Oxygen Uptake Computer

868.2375 Breathing Frequency Monitor

868.2450 Lung Water Monitor

868.5160 Gas Machine for Anesthesia or Analgesia

868.5330 Breathing Gas Mixer

868.5400 Electroanesthesia Apparatus

868.5440 Portable Oxygen Generator

868.5470 Hyperbaric Chamber

868.5610 Membrane Lung (for Long-Term Pulmonary Support)

868.5830 Autotransfusion Apparatus

868.5880 Anesthetic Vaporizer

868.5895 Continuous Ventilator

868.5925 Powered Emergency Ventilator

868.5935 External Negative Pressure Ventilator

868.5955 Intermittent Mandatory Ventilation Attachment

870.1025 Arrhythmia Detector and Alarm

870.1750 External Programmable Pacemaker Pulse Generator

870.3535 Intra-aortic Balloon and Control System

870.3545 Ventricular Bypass (Assist) Device

870.3600 External Pacemaker Pulse Generator

870.3610 Implantable Pacemaker Pulse-Generator

870.3700 Pacemaker Programmers

870.4220 Cardiopulmonary Bypass Heart-Lung Machine Console

870.4320 Cardiopulmonary Bypass Pulsatile Flow Generator

870.4330 Cardiopulmonary Bypass On-Line Blood Gas Monitor

870.4360 Nonroller-Type Cardiopulmonary Bypass Blood Pump

870.4370 Roller-Type Cardiopulmonary Bypass Blood Pump

870.4380 Cardiopulmonary Bypass Pump Speed Control

870.5225 External Counter-Pulsating Device

870.5300 DC-Defibrillator Low Energy (Including Paddles)

876.5270 Implanted Electrical Urinary Continence Device

876.5630 Peritoneal Dialysis System and Accessories

876.5820 Hemodialysis System and Accessories

876.5860 High Permeability Hemodialysis System

876.5870 Sorbent Hemoperfusion System

876.5880 Isolated Kidney Perfusion and Transport System and Accessories

880.5130 Infant Radiant Warmer

880.5400 Neonatal Incubator

880.5410 Neonatal Transport Incubator

880.5725 Infusion Pump

882.5820 Implanted Cerebellar Stimulator

882.5830 Implanted Diaphragmatic/Phrenic Nerve Stimulator

882.5840 Implanted Intracerebral/Subcortical Stimulator For Pain Relief

882.5850 Implanted Spinal Cord Stimulator for Bladder Evacuation

882.5860 Implanted Neuromuscular Stimulator

882.5870 Implanted Peripheral Nerve Stimulator for Pain Relief

882.5880 Implanted Spinal Cord Stimulator for Pain Relief

884.1700 Hysteroscopic Insufflator

884.1730 Laparoscopic Insufflator

884.2660 Fetal Ultrasonic Monitor and Accessories

892.5050* Medical Charged-Particle Radiation Therapy System

892.5300* Medical Neutron Radiation Therapy System

892.5700* Remote Controlled Radionuclide Applicator System

892.5750* Radionuclide Radiation Therapy System

892.5900* X-ray Radiation Therapy System

* The device classifications specified previously with an asterisk include radiation treatment planning systems that are accessories to these device types.

*B. Post Medical Device Amendments Class III Devices and Devices not yet Classified*

Automated Blood Cell and Plasma Separator for Therapeutic Purposes

Cardioconverter, Implantable

Defibrillator, Automatic Implantable Cardioverter

Defibrillator, Implantable, Dual-Chamber

Device, Thermal Ablation, Endometrial

Kit, Test, Alpha-Fetoprotein for Neural Tube Defects

Lipoprotein, Low Density, Removal

Pulse-Generator, Dual Chamber, Implantable

Pulse-Generator, Program Module

Pulse-Generator, Single Chamber

Pulse-Generator, Single Chamber, Sensor Driven, Implantable

Pump, Drug Administration, Closed Loop

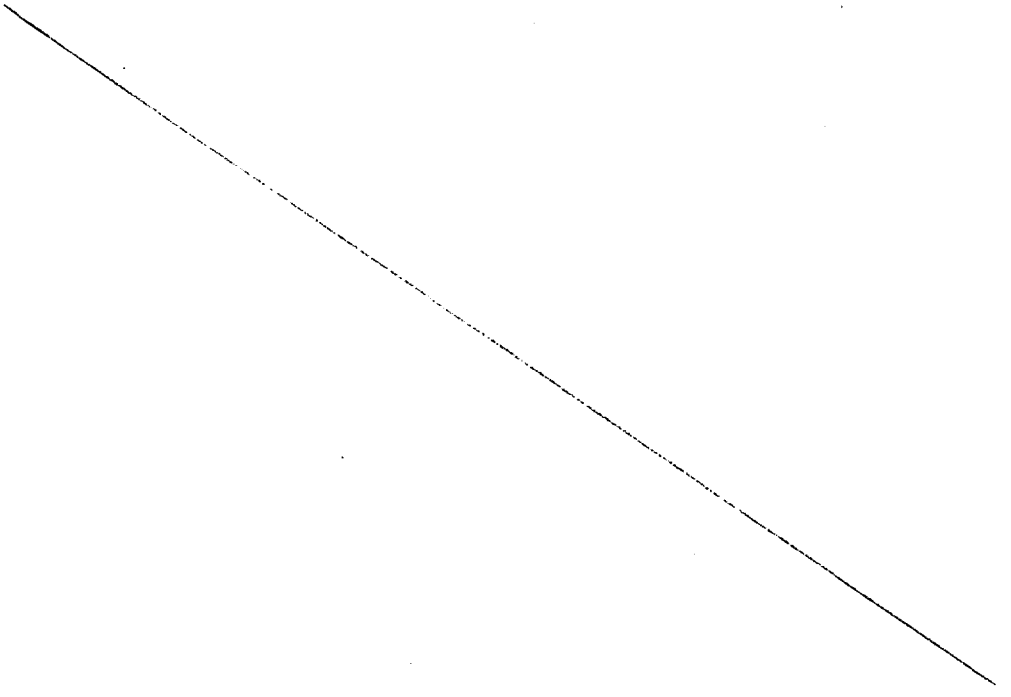
Pump, Infusion, Implanted, Programmable

Separator for Therapeutic Purposes, Membrane Automated Blood Cell/Plasma

Stimulator, Cortical, Implanted (for Pain)

Stimulator, Electrical, Implanted, for Parkinsonian Tremor

Stimulator, Sacral Nerve, Implanted



Stimulator, Spinal-Cord, Totally Implanted for Pain Relief

Stimulator, Subcortical, Implanted for Epilepsy

System, Pacing, Temporary, Acute, Internal Atrial Defibrillation

Ventilator, High Frequency

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CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

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